



Universiteit  
Leiden  
The Netherlands

## **A fair balance: health data protection and the promotion of health data use for clinical and research purposes**

Kist, I.R.

### **Citation**

Kist, I. R. (2024, June 5). *A fair balance: health data protection and the promotion of health data use for clinical and research purposes*. Retrieved from <https://hdl.handle.net/1887/3759726>

Version: Publisher's Version

License: [Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden](#)

Downloaded from: <https://hdl.handle.net/1887/3759726>

**Note:** To cite this publication please use the final published version (if applicable).

## 8. Bibliography

- Abboud, L., Bogaert, P., Bowers, S., Clissold, H., Cosgrove, S., Kesisoglou, I., Richards, R., Pinto, C., Saso, M., & Soares, F. (2022, February 28). *Report on secondary use of health data through European case studies*. Towards European Health Data Space Consortium Partners. <https://tehdas.eu/app/uploads/2022/08/tehdas-report-on-secondary-use-of-health-data-through-european-case-studies-.pdf>
- Abboud, L., Cosgrove, S., Kesisoglou, I., Richards, R., & Soares, F. (2021, September 28). *Summary of milestone 5.1 & 5.2. Annex A | Case studies: Different governance and health data systems in Europe*. TEHDAS Consortium Partners. <https://tehdas.eu/app/uploads/2021/09/tehdas-annex-a-case-studies-different-governance-and-health-data-systems-in-europe-2021-09-28.pdf>
- Akkermans, A. J. (2002). *De 'omkeringsregel' bij het bewijs van causaal verband*. Boom.
- Algra, K. A., Bouter, L. M., Hol, A. M., & van Kreveld, J. (2018). *Nederlandse gedragscode wetenschappelijke integriteit*. <https://doi.org/10.17026/dans-2cj-nvwu>
- All European Academies. (2017). *European Code of Conduct for Research Integrity* (Revised edition). <https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf>
- Autoriteit Persoonsgegevens. (2017) *Onderzoeksrapport Alcohol- en drugscontroles bij werknemers. De verwerking van persoonsgegevens bij de uitvoering van alcohol- en drugscontroles door Uniper Benelux N.V.* [https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/01\\_rapport\\_db\\_uniper\\_def.pdf](https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/01_rapport_db_uniper_def.pdf)
- Autoriteit Persoonsgegevens. (2018). *Data Protection Authority supervisory framework: Principles for supervision 2018–2019*. [https://www.autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/data\\_protection\\_authority\\_supervisory\\_framework\\_2018-2019.pdf](https://www.autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/data_protection_authority_supervisory_framework_2018-2019.pdf)
- Autoriteit Persoonsgegevens. (2022, March 15). *AP inzet artificial intelligence act*. [https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/ap\\_inzet\\_ai\\_act.pdf](https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/ap_inzet_ai_act.pdf)
- Autoriteit Persoonsgegevens. (2023, February 13). *Brief adviesverzoek onderzoek oversterfte* <https://www.autoriteitpersoonsgegevens.nl/nl/nieuws/ap-onderzoek-naar-oversterfte-kan-cbs>.
- BBMRI-ERIC. (n.d.). *Response by BBMRI-ERIC to “European Health Data Space” (EHDS) Questionnaire (Public Consultation)*. <https://www.bbMRI-eric.eu/wp-content/uploads/bbMRI-eric-response-to-ehds-statement.pdf>
- BBMRI-ERIC. (n.d.). *Statement by BBMRI-ERIC on “A European Health Data Space.”* <https://www.bbMRI-eric.eu/wp-content/uploads/statement-on-european-health-data-space.pdf>
- BBMRI-ERIC. (n.d.). *Code of Conduct for Health Research: A collaborative approach to EU health GDPR*. <https://code-of-conduct-for-health-research.eu/>
- Beauvais, M. (2021, February 1). *GA4GH GDPR Brief: The public interest and the GDPR*. <https://www.ga4gh.org/news/ga4gh-gdpr-brief-the-public-interest-and-the-gdpr-february-2021/>
- Becker, M. (2018). Understanding users' health information privacy concerns for health wearables. In *Proceedings of the 51st Hawaii International Conference on System Sciences* (pp. 3261-3270). IEEE. <https://scholarspace.manoa.hawaii.edu/items/1d172717-15d5-455e-83e7-6afe4e891ab8>
- Becker, R., Chokoshvili, D., Comandé, G., Dove, E., Hall, A., Mitchell, C., Molnar-Gabor, F., Nicolás, P., Tervo, S., & Thorogood, A. (2022). Secondary use of personal health data: When is it 'further processing' under the GDPR, and what are the implications for data controllers? *European Journal of Health Law*, 29, 1-29. <https://doi.org/10.1163/15718093-bja10094>
- Becker, R., Thorogood, A., Bovenberg, J., Mitchell, C., & Hall, A. (2022). Applying GDPR roles and responsibilities to scientific data sharing. *International Data Privacy Law*, 12(3), 207-219. <https://doi.org/10.1093/idpl/ipac011>

- Becker, R., Thorogood, A., Ordish, J., & Beauvais, M. J. S. (2020). COVID-19 research: Navigating the European general data protection regulation. *Journal of Medical Internet Research*, 22(8), e19799. <https://doi.org/10.2196/19799>
- Boeckhout, M., Beusink, M., & Bouter, L. (2020, February 14). *Niet-WMO-plichtig onderzoek en ethische toetsing*. Ministerie van Volksgezondheid, Welzijn en Sport. <https://www.coreon.org/wp-content/uploads/2020/07/Verkenning-nWMO-onderzoek-DEF.pdf>
- Boyd, M., Zimeta, M., Tennison, J., & Alassow, M. (2021). *Secondary use of health data in Europe*. Open Data Institute. <https://theodi.org/wp-content/uploads/2021/09/Secondary-use-of-Health-Data-In-Europe-ODI-Roche-Report-2021-5.pdf>
- Breitbarth, P. (2021). A risk-based approach to international data transfers. *European Data Protection Law Review*, 7(4), 539-547. <https://doi.org/10.21552/edpl/2021/4/9>
- Broeders, D., Cuijpers, M. K. C., & Prins, J. E. J. (2011). *De staat van informatie*. Amsterdam University Press.
- Bruins, B. J. (2019, May 7). *Patiënten- en cliëntenrechten; Briefregering' Voorgangsrapportage Ontwikkeling Uitkomstgerichte Zorg 2018-2022*. <https://zoek.officielebekendmakingen.nl/kst-31476-28.pdf>
- Carter, P., Laurie, G. T., & Dixon-Woods, M. (2015). The social licence for research: Why care.data ran into trouble. *Journal of Medical Ethics*, 41(5), 404-409. <https://doi.org/10.1136/medethics-2014-102374>
- Centrale Commissie Mensgebonden Onderzoek. (n.d.). *Uw onderzoek: WMO-plichtig of niet?* Retrieved from <https://www.ccmo.nl/onderzoekers/wet-en-regelgeving-voor-medisch-wetenschappelijk-onderzoek/uw-onderzoek-wmo-plichtig-of-niet>
- Chico, V. (2018). The impact of the general data protection regulation on health research. *British Medical Bulletin*, 128(1), 109-118. <https://doi.org/10.1093/bmb/ldy038>
- College bescherming persoonsgegevens (2014). *Onderzoek naar de toestemming voor de uitwisseling van medische persoonsgegevens via het Landelijk Schakelpunt*. 2012-779
- Comandè, G., & Schneider, G. (2022). Differential data protection regimes in data-driven research: Why the GDPR is more research-friendly than you think. *German Law Journal*, 23(4), 559-596. <https://doi.org/10.1017/glj.2022.30>
- Commissie Regelgeving Onderzoek. (2019). *Herziening Gedragscode gezondheidsonderzoek: Plan van Aanpak*. <https://www.medlaw.nl/wp-content/uploads/2019/10/PvAherzieningGedragscodeGezondheidsonderzoek51.pdf>
- Commissie Governance van Kwaliteitsregistraties. (2019, March 29). *Advies Commissie Governance van Kwaliteitsregistraties*. [https://www.ordz.nl/binaries/ordz/documenten/publicaties/2019/07/22/advies-commissie-governance-van-kwaliteitsregistraties/Advies\\_commissie\\_governance\\_van\\_kwaliteitsregistraties.pdf](https://www.ordz.nl/binaries/ordz/documenten/publicaties/2019/07/22/advies-commissie-governance-van-kwaliteitsregistraties/Advies_commissie_governance_van_kwaliteitsregistraties.pdf)
- Consolidated version of the Treaty on the Functioning of the European Union. (2012, October 26). <https://www.refworld.org/pdfid/52303e8d4.pdf>
- Coppen, R., Groenewegen, P. P., Hazes, J. M. W., de Jong, J. D., Kievit, J., de Neeling, J., Reijneveld, S. A., Verheij, R. A., & Vroom, E. (2016). Hergebruik van medische gegevens voor onderzoek: Wat vindt de Nederlander van het toestemmingsvereiste? *Nederlands Tijdschrift voor Geneeskunde*, 160(15), 17-23. <https://postprint.nivel.nl/PPpp6202.pdf>
- COREON. (2022, January). *Gedragscode gezondheidsonderzoek*. <https://www.coreon.org/wp-content/uploads/2022/01/Gedragscode-Gezondheidsonderzoek-2022.pdf>
- Cornel, M. C., Ploem, C., & Gevers, J. K. M. (2019). Commercieel aanbod van DNA-tests: Ruim baan voor vrije markt en zelfbeschikking? *Nederlands Juristenblad*, 32, 2364-2371. <https://researchinformatie.amsterdamumc.org/en/publications/commercieel-aanbod-van-dna-tests-ruim-baan-voor-vrije-markt-en-ze-2>

- Council of Europe. (1950). *European Convention for the Protection of Human Rights and Fundamental Freedoms*. [https://www.echr.coe.int/documents/convention\\_eng.pdf](https://www.echr.coe.int/documents/convention_eng.pdf)
- Council of Europe. (1981). *Convention for the protection of individuals with regard to automatic processing of personal data*. <https://rm.coe.int/1680078b37>
- Council of Europe. (1997). *Convention for the protection of human rights and dignity of human being with regard to the application of biology and medicine: Convention on human rights and biomedicine*. <https://rm.coe.int/168007cf98>
- Council of Europe. (2001). *Additional Protocol to the Convention for the protection of individuals with regard to automatic processing of personal data, regarding supervisory authorities and trans-border data flows*. <https://rm.coe.int/1680080626>
- Council of Europe. (2016, May 30). *Recommendation CM/Rec (2016) 6 of the Committee of Ministers to member states on research on biological materials of human origin*. [https://www.isciii.es/QueHacemos/Servicios/ComitesEtica/CEI/Documents/Recommendation\\_CM\\_Rec-2016-6.pdf](https://www.isciii.es/QueHacemos/Servicios/ComitesEtica/CEI/Documents/Recommendation_CM_Rec-2016-6.pdf)
- Council of Europe. (2018). *Additional Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data*. <https://rm.coe.int/16808ac918>
- Council of Europe. (2019, March 27). *Recommendation CM/Rec (2019) 2 of the Committee of Ministers to member states on the protection of health-related data*. <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168093b26e>
- Council of Europe. (2022, August 31). *Guide on Article 8 of the European Convention on Human Rights: Right to respect for private and family life, home and correspondence*. [https://www.echr.coe.int/documents/guide\\_art\\_8\\_eng.pdf](https://www.echr.coe.int/documents/guide_art_8_eng.pdf)
- Court of Justice of the European Union. (2021, November). *Factsheet on protection of personal data*. [https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-10/fiche\\_thematique\\_-\\_donnees\\_personnelles\\_-\\_en.pdf](https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-10/fiche_thematique_-_donnees_personnelles_-_en.pdf)
- D'Abramo, F., Schildmann, J., & Vollmann, J. (2015). Research participants' perceptions and views on consent for biobank research: A review of empirical data and ethical analysis. *BMC Medical Ethics*, 16, Article 60. <https://doi.org/10.1186/s12910-015-0053-5>
- De Hert, P. D., & Gutwirth, S. (2009). Data protection in the case law of Strasbourg and Luxembourg: Constitutionalisation in action. In S. Gutwirth, Y. Pouillet, P. De Hert, C. de Terwangne, & S. Nouwt (Eds.), *Reinventing data protection?* (pp. 3-44). Springer.
- De Hert, P., & Gutwirth, S. (2006). Privacy, data protection and law enforcement. Opacity of the individual and transparency of power. In E. Claes, A. Duff., & S. Gutwirth (Eds.), *Privacy and the criminal law* (pp. 61-104). Intersentia.
- De Jonge, H. M., & Knops, R. W. (2021, May 26). *Regels voor handelingen met lichaamsmateriaal, welke worden verricht voor andere doeleinden dan geneeskundige behandeling of diagnostiek van de donor (Wet zeggenschap lichaamsmateriaal)*. <https://zoek.officielebekendmakingen.nl/dossier/kst-35844-2.pdf>
- De Valck, C., Bensing, J., Bruynooghe, R., & Batenburg, V. (2001). Cure-oriented versus care-oriented attitudes in medicine. *Patient Education and Counseling*, 45(2), 119-126. [https://doi.org/10.1016/S0738-3991\(00\)00201-9](https://doi.org/10.1016/S0738-3991(00)00201-9)
- Dekker, S. (2020, 4 juni). *Wijziging uitvoeringswet AVG c.a.* [Letter to Parliament]. Retrieved from <https://open.overheid.nl/repository/rnl-9b1c268f-97a7-401a-81eb-f0babaecabc6/1/pdf/tk-wijziging-uitvoeringswet-avg-c-a.pdf>
- Dekker, S., Knops, R. W., & Ollongren, K. H. (2017, December 12). *Regels ter uitvoering van Verordening (EU) 2016/679 van het Europees Parlement en de Raad van 27 april 2016 betreffende de bescherming van natuurlijke personen in verband met de verwerking van persoonsgegevens en betreffende het vrije verkeer van die gegevens en tot intrekking van Richtlijn 95/46/EG (algemene verordening gegevens-*

- bescherming*) (PbEU 2016, L 119) (Uitvoeringswet Algemene verordening gegevensbescherming). <https://zoek.officielebekendmakingen.nl/kst-34851-3.pdf>
- Department for Digital, Culture, Media & Sport. (2020, December 9). *Policy paper: UK National Data Strategy*. <https://open.overheid.nl/repository/ronl-9b1c268f-97a7-401a-81eb-f0babaecabc6/1/pdf/tk-wijziging-uitvoeringswet-avg-c-a.pdf>
- Department for Digital, Culture, Media & Sport. (2022, June 23). *Data: A new direction. Government response to consultation*. <https://www.gov.uk/government/consultations/data-a-new-direction/outcome/data-a-new-direction-government-response-to-consultation>
- Digital Health Europe. (2021). *Recommendations on the European Health Data Space. Supporting responsible health data sharing and use through governance, policy and practice*. [https://digitalhealtheuropa.eu/wp-content/uploads/DHE\\_recommendations\\_on\\_EHDS\\_July\\_2021.pdf](https://digitalhealtheuropa.eu/wp-content/uploads/DHE_recommendations_on_EHDS_July_2021.pdf)
- Donnelly, M., & McDonagh, M. (2019). Health research, consent and the GDPR exemption. *European Journal of Health Law*, 26(2), 97-119. <https://doi.org/10.1163/15718093-12262427>
- Dörenberg, V. E. T., & Hendriks, A. C. (2011). Grondrechten in de gezondheidszorg. Liber Amicorum voor prof. mr. J.K.M. Gevers. *Tijdschrift voor Gezondheidsrecht*, 7, 625-628. <https://research.vu.nl/ws/portalfiles/portal/3042036/281051.pdf>
- Dove, E. S. (2018). The EU general data protection regulation: Implications for international scientific research in the digital era. *Journal of Law, Medicine & Ethics*, 46(4), 1013-1030. <https://doi.org/10.1177/1073110518822>
- Dove, E. S. (2019, August 5). *GDPR brief: Codes of conduct under the GDPR: A useful but challenging tool to enable responsible international data sharing*. Global Alliance for Genomics & Health. <https://www.ga4gh.org/news/gdpr-brief-codes-of-conduct-under-the-gdpr-a-useful-but-challenging-tool-to-enable-responsible-international-data-sharing/>
- Dove, E. S. (2021, May 17). *GDPR brief: Finding a route out of the impasse? Ordering the secondary processing of already gathered data in a Code of Conduct*. Global Alliance for Genomics & Health. <https://www.ga4gh.org/news/finding-a-route-out-of-the-impasse/>
- Dove, E. S., & Chen, J. (2020). Should consent for data processing be privileged in health research? A comparative legal analysis. *International Data Privacy Law*, 10(2), 117-131. <https://doi.org/10.1093/idpl/ipz023>
- Dröge, C. (2003). *Positive Verpflichtungen der Staaten in der Europäischen Menschenrechtskonvention*. Springer.
- Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P., Cording, E., Tomson, D., Dodd, C., Rollnick, S., Edwards, A., & Barry, M. (2012). Shared decision making: A model for clinical practice. *Journal of General Internal Medicine*, 27(10), 1361-1367. <https://doi.org/10.1007/s11606-012-2077-6>
- Engberts, D. P., & Kalkman-Bogerd, L. E. (2009). *Gezondheidsrecht*. Bohn Stafleu van Loghum.
- Entwistle, V. A., Carter, S. M., Cribb, A., & McCaffery, K. (2010). Supporting patient autonomy: The importance of clinician-patient relationships. *Journal of General Internal Medicine*, 25(7), 741-745. <https://doi.org/10.1007/s11606-010-1292-2>
- European Commission. (2014, April 10). *Commission Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps accompanying the document Green Paper on mobile Health ("mHealth")*. <https://op.europa.eu/o/opportal-service/download-handler?identifier=8dcf22a2-c091-11e3-86f9-01aa75ed71a1&format=pdf1x&language=en&productionSystem=cellar&part=>
- European Commission. (2015, May 6). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A*

- digital single market strategy for Europe COM 192 final*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0192&from=EN>
- European Commission. (2016, March). *Patients' Rights in the European Union Mapping eXercise*. [http://www.activecitizenship.net/multimedia/import/files/patients\\_rights/charter-of-rights/publications-of-the-charter/Patients\\_Rights\\_in\\_the\\_European\\_Union.pdf](http://www.activecitizenship.net/multimedia/import/files/patients_rights/charter-of-rights/publications-of-the-charter/Patients_Rights_in_the_European_Union.pdf)
- European Commission. (2020a, June 24). *Communication from the Commission to the European Parliament and the Council. Data protection as a pillar of citizens' empowerment and the EU's approach to the digital transition: Two years of application of the General Data Protection Regulation*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0264&from=EN>
- European Commission. (2020b, November 25). *Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act)*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0767&from=EN>
- European Commission. (2020c). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A European strategy for data*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN>
- European Commission. (2021a). *Assessment of the EU Member States' rules on health data in the light of GDPR*. <https://doi.org/10.2818/546193>
- European Commission. (2021b, February). *Horizon Europe: strategic plan 2021-2024*. [https://www.eeas.europa.eu/sites/default/files/horizon\\_europe\\_strategic\\_plan\\_2021-2024.pdf](https://www.eeas.europa.eu/sites/default/files/horizon_europe_strategic_plan_2021-2024.pdf)
- European Commission. (2021c). *Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts*. [https://eur-lex.europa.eu/resource.html?uri=cellar:e0649735-a372-11eb-9585-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:e0649735-a372-11eb-9585-01aa75ed71a1.0001.02/DOC_1&format=PDF)
- European Commission. (2022a, March 23). *Proposal for a regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act)*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022PC0068&from=EN>
- European Commission. (2022b, May 13). *Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare*. [https://health.ec.europa.eu/system/files/2022-05/ncd\\_20220519\\_ag\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2022-05/ncd_20220519_ag_en_0.pdf)
- European Commission. (2022c, May 3). *Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space*. [https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF)
- European Commission. (2022d, May 3). *Proposal for a Regulation of the European Parliament and of the Council of 3 May 2022 on the European Health Data Space (Text with EEA relevance)*. [https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF)
- European Commission. (2022e, May 3). *Questions and answers – EU Health: European Health Data Space (EHDS)*. [https://health.ec.europa.eu/latest-updates/questions-and-answers-eu-health-european-health-data-space-ehds-2022-05-03\\_en](https://health.ec.europa.eu/latest-updates/questions-and-answers-eu-health-european-health-data-space-ehds-2022-05-03_en)
- European Commission. (n.d.). *ECIS - European Cancer Information System*. Retrieved from <https://ecis.jrc.ec.europa.eu/>
- European Medicines Agency. (2015). *ICH E6 (R2) Good clinical practice: Scientific guideline*. <https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice-scientific-guideline>
- European Medicines Agency. (z.d.). *Clinical trial*. In *Glossary*. <https://www.ema.europa.eu/en/glossary/clinical-trial>

- European Parliament and the Council. (1995, October 24). *Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995L0046&from=EN>
- European Parliament. (2000, October 11). *Explanations Relating to the Charter of Fundamental Rights of the European Union*. [https://www.europarl.europa.eu/charter/pdf/04473\\_en.pdf](https://www.europarl.europa.eu/charter/pdf/04473_en.pdf)
- European Parliament. (2022a, October). *Fostering coherence in EU health research. Strengthening EU research for better health*. [https://www.europarl.europa.eu/RegData/etudes/STUD/2022/737114/EPRS\\_STU\(2022\)737114\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2022/737114/EPRS_STU(2022)737114_EN.pdf)
- European Parliament. (2022b). *Legislative train schedule: Promoting our European way of life after 2022-01*. <https://www.europarl.europa.eu/legislative-train/>
- European Union (Withdrawal) Act. (2018, June 26). <https://www.legislation.gov.uk/ukpga/2018/16/contents/enacted>
- European Union. (2011, April 4). *Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN>
- European Union. (2012a, October 26). *Charter of Fundamental Rights of the European Union*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:C2012/326/02>
- European Union. (2012b, October 26). *Consolidated Version of the Treaty on the Functioning of the European Union*. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:en:PDF>
- European Union. (2014, April 16). *Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536>
- European Union. (2016, May 4). *Regulation (EU) No. 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC*. <https://op.europa.eu/o/opportal-service/download-handler?identifier=3e485e15-11bd-11e6-ba9a-01aa75ed71a1&format=pdfa1a&language=en&productionSystem=cellar&part=>
- European Union. (2017, May 5). *Regulation (EU) No. 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN>
- Europees Hof voor de Rechten van de Mens. (1997). *Series A vol. 335-C*. <https://uitspraken.rechtspraak.nl/#!/details?id=ECLI:NL:XX:1995:AD2430>
- Federatie Medische Specialisten, Nederlandse Federatie van Universitair Medisch Centra, Commissie Regelgeving Onderzoek, & Health RI. (2021). *Inbreng op wetsvoorstel 'Wet zeggenschap lichaamsmateriaal'*. <https://www.health-ri.nl/sites/healthri/files/2021-09/Inbreng%20WZL%20-%20NFU%2C%20FMS%2C%20Health-RI%2C%20COREON.pdf>
- Fiene, R. J. (2019). A treatise on regulatory compliance. *Journal of Regulatory Science*, 7(1) 1–3. <https://doi.org/10.21423/jrs-v07fiene>
- Filipe A., Renedo A., Marston C. (2017). The co-production of what? Knowledge, values, and social relations in health care. *PLOS Biology* 15(5): e2001403. <https://doi.org/10.1371/journal.pbio.2001403>
- Finck, M., & Pallas, F. (2020). They who must not be identified: Distinguishing personal from non-personal data under the GDPR. *International Data Privacy Law*, 10(1), 11-36. <https://doi.org/10.1093/idpl/ipz026>

- Forcier, M. B., Gallois, H., Mullan, S., & Joly, Y. (2019). Integrating artificial intelligence into health care through data access: Can the GDPR act as a beacon for policymakers? *Journal of Law and the Biosciences*, 6(1), 317-335. <https://doi.org/10.1093/jlb/lisz013>
- Fraser, E. E. (2003). The dimensions of human rights: A confirmatory factor analysis of human rights provisions. *International Journal of Sociology*, 33(4), 11-40. <https://doi.org/10.1080/15579336.2003.11770274>
- Gefenas, E., Lekstutiene, J., Lukaseviciene, V., Hartlev, M., Mourby, M., & Cathaoir, K. Ó. (2022). Controversies between regulations of research ethics and protection of personal data: Informed consent at a cross-road. *Medicine, Health Care and Philosophy*, 25(1), 23-30. <https://doi.org/10.1007/s11019-021-10060-1>
- Gerrits, E. M., van Dooren, M. F., Bredenoord, A. L., & van Mil, M. H. W. (2019). Direct-to-consumer genetic tests in de spreekkamer. *Nederlands Tijdschrift voor Geneeskunde*, 163, Article D4131.
- Gerritsen, J., & Verhoef, P. (2020). *Datasolidariteit voor gezondheid: verbeterpunten met oog voor ieders belang*. Rathenau Instituut. [https://www.rathenau.nl/sites/default/files/2020-12/Rathenau%20Instituut\\_Rapport\\_Datasolidariteit%20voor%20gezondheid.pdf](https://www.rathenau.nl/sites/default/files/2020-12/Rathenau%20Instituut_Rapport_Datasolidariteit%20voor%20gezondheid.pdf)
- González Fuster, G. (2022). Study on the essence of the fundamental rights to privacy and to protection of personal data. *EDPS 2021/0932*. [https://edps.europa.eu/system/files/2023-11/edps-vub-study\\_on\\_the\\_essence\\_of\\_fundamental\\_rights\\_to\\_privacy\\_and\\_to\\_protection\\_of\\_personal\\_data\\_en.pdf](https://edps.europa.eu/system/files/2023-11/edps-vub-study_on_the_essence_of_fundamental_rights_to_privacy_and_to_protection_of_personal_data_en.pdf)
- Grisso, T., & Appelbaum, P. S. (1995). Comparison of standards for assessing patients' capacities to make treatment decisions. *American Journal of Psychiatry*, 152(7), 1033-1037. <https://doi.org/10.1176/ajp.152.7.1033>
- Hallinan, D. (2020). Broad consent under the GDPR: An optimistic perspective on a bright future. *Life Sciences, Society and Policy*, 16(1), Article 1. <https://doi.org/10.1186/s40504-019-0096-3>
- Hallinan, D. (2020). The genomic data deficit: On the need to inform research subjects of the informational content of their genomic sequence data in consent for genomic research. *Computer Law & Security Review*, 37, Article 105427. <https://doi.org/10.1016/j.clsr.2020.105427>
- Health-RI. (2021, October). *Afsprakenstelsel Health-RI. Ambitie, Uitgangsprincipes, Obstakels, Oplossingsrichtingen*. <https://www.health-ri.nl/sites/healthri/files/2021-11/Afsprakenstelsel%20Health-RI%20Groeifonds%20project%20-%20Ambitie%2C%20Obstakels%2C%20Oplossingsrichtingen%2C%20Governance.pdf>
- Helsper, C. C., van Erp, N. N., Peeters, P. P., & de Wit, N. N. (2017). Time to diagnosis and treatment for cancer patients in the Netherlands: Room for improvement? *European Journal of Cancer*, 87, 113-121. <https://doi.org/10.1016/j.ejca.2017.10.003>
- Hendriks, A. C. (2001). Het medisch beroepsgeheim. Enige actuele dilemma's. *NCJM Bulletin*, 26(5), 525-538. [https://njcm.nl/wp-content/uploads/ntm/T2b\\_NTM2FNJCM-bull2E\\_010534\\_Final\\_LR.pdf](https://njcm.nl/wp-content/uploads/ntm/T2b_NTM2FNJCM-bull2E_010534_Final_LR.pdf)
- Hendriks, A. C. (2021). Europeesrechtelijke dimensies van het gezondheidsrecht: de vooruitziende blik van Leenen (Henk Leenenlezing, 2020). *Tijdschrift voor Gezondheidsrecht*, 45(2), 131-140. [https://www.vereniginggezondheidsrecht.nl/uploads/Over%20de%20VGR/Leenenlezingen/Europeesrechtelijke\\_dimensies\\_van\\_het\\_gezondheidsrecht.pdf](https://www.vereniginggezondheidsrecht.nl/uploads/Over%20de%20VGR/Leenenlezingen/Europeesrechtelijke_dimensies_van_het_gezondheidsrecht.pdf)
- Hendriks, A. C., Frederiks, B. D., & Verkerk, M. A. (2008). Het recht op autonomie in samenhang met goede zorg bezien. *Tijdschrift voor Gezondheidsrecht*, 32(1), 2-18. <https://research.vumc.nl/ws/files/834518/287624.pdf>
- Hendriks, A. C., Friele, R. D., Legemaate, J., & Widdershoven, G. A. M. (2013, September 13). *Thematische wetsevaluatie Zelfbeschikking in de zorg*. ZonMw.

- Hess, D. R. (2004). Retrospective studies and chart reviews. *Respiratory Care*, 49(10), 1171-1174. <https://rc.rcjournal.com/content/respcare/49/10/1171.full.pdf>
- Hijmans, H., & Raab, C. D. (2018, July 30). Ethical dimensions of the GDPR. In M. Cole & F. Boehm (Eds.), *Commentary on the general data protection regulation*. Edward Elgar.
- Hildebrandt, M. (2020). *Law for computer scientists and other folk*. Oxford University Press.
- Hirsch Ballin, E. M. H., & Simons, H. J. (2020, June 2). *Wijziging van het Burgerlijk Wetboek en enige andere wetten in verband met de opnemng van bepalingen omtrent de overeenkomst tot het verrichten van handelingen op het gebied van de geneeskunst*. [https://repository.overheid.nl/frbr/sgd/19891990/0000041060/1/pdf/SGD\\_19891990\\_0006449.pdf](https://repository.overheid.nl/frbr/sgd/19891990/0000041060/1/pdf/SGD_19891990_0006449.pdf)
- Holm, S., Kristiansen, T. B., & Ploug, T. (2021). Control, trust and the sharing of health information: The limits of trust. *Journal of Medical Ethics*, 47, Article 35. <https://doi.org/10.1136/medethics-2019-105887>
- Hoofnagle, C. J., van der Sloot, B., & Borgesius, F. Z. (2019). The European Union general data protection regulation: What it is and what it means. *Information & Communications Technology Law*, 28(1), 65-98. <https://doi.org/10.1080/13600834.2019.1573501>
- Hooghiemstra, T. (2018). *Informationele zelfbeschikking in de zorg*. SDU.
- Hooghiemstra, T. (2019). Informational self-determination, digital health and new features of data protection. *European Data Protection Law Review*, 5(2), 160-174. <https://doi.org/10.21552/edpl/2019/2/6>
- Hooghiemstra, T., & Lokin, M. (2021, May 11). Persoonsgegevens zijn niet altijd taboe in medisch onderzoek. *NRC*. <https://www.nrc.nl/nieuws/2021/05/11/persoonsgegevens-zijn-niet-altijd-taboe-in-medisch-onderzoek-a4043178>
- Hooghiemstra, T., Blok, P., Moerel, L., Olsthoorn, P., Purtova, N., & Tjong Tjin Tai, E. (2021, October 29). *Overwegingen en suggesties voor beleid*. <https://www.tweedekamer.nl/downloads/document?id=a514eed6-4b23-4b03-b6af-0c8159b7f872>
- Hornung, G., & Schnabel, C. (2009). Data protection in Germany I: The population census decision and the right to informational self-determination. *Computer Law & Security Review*, 25(1), 84-88. <https://doi.org/10.1016/j.clsr.2008.11.002>
- Hoytema van Konijnenburg, E. M., Teeuw, A. H., & Ploem, M. C. (2015). Data research on child abuse and neglect without informed consent? Balancing interests under Dutch law. *European Journal of Pediatrics*, 174(12), 1573-1578. <https://doi.org/10.1007/s00431-015-2649-7>
- Hsu, P. J., Wu, C. Y., Kuo, L. C., Chen, M. Y., Chen, Y. L., Huang, S. F., Chuang, P.-Y., Jerng, J.-Sh., & Chen, S. Y. (2022). Improving the process of shared decision-making by integrating online structured information and self-assessment tools. *Journal of Personalized Medicine*, 12(2), Article 256. <https://doi.org/10.3390/jpm12020256>
- Hustinx, P. (2014, September 8). *European leadership in privacy and data protection*. [https://edps.europa.eu/sites/default/files/publication/14-09-08\\_article\\_uji\\_castellon\\_en.pdf](https://edps.europa.eu/sites/default/files/publication/14-09-08_article_uji_castellon_en.pdf)
- Information Commissioner's Office. (2021, December 6). *Response to DCMS consultation "Data: a new direction."* <https://ico.org.uk/media/about-the-ico/consultation-responses/4018588/dcms-consultation-response-20211006.pdf>
- Kalkman, S., van Delden, J., Banerjee, A., Tyl, B., Mostert, M., & van Thiel, G. (2022). Patients' and public views and attitudes towards the sharing of health data for research: A narrative review of the empirical evidence. *Journal of Medical Ethics*, 48(1), 3-13. <https://doi.org/10.1136/medethics-2019-105651>
- Kalliola, M., Drakvik E. & Nurmi, M. (Eds.) (2023, September), 'Advancing data sharing to improve health for all in Europe'. *Sitra Studies* 236. <https://www.sitra.fi/en/publications/advancing-data-sharing-to-improve-health-for-all-in-europe/>

- Kamara, I., & De Hert, P. (2018). Understanding the balancing act behind the legitimate interest of the controller ground: A pragmatic approach. *Brussels Privacy Hub*, 4(12). <http://doi.org/10.2139/ssrn.3228369>
- Kamerstukken II, 36278. (2022, December 16). <https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?cfg=wetsvoorsteldetails&qry=wetsvoorstel%3A36278>
- Kamerstukken II, 35844. (2021, May 27). <https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?qry=wetsvoorstel%3A35844&cfg=wetsvoorsteldetails#:~:text=Deze%20wet%20stelt%20voorwaarden%20waaronder,nader%20gebruik%20van%20zijn%20lichaamsmateriaal.>
- Kamerstukken II, 27529 (2021, May 12). <https://zoek.officielebekendmakingen.nl/kst-27529-276.html>
- Kamerstukken II, 35824 (2021, May 3). <https://www.tweedekamer.nl/kamerstukken/wetsvoorstellen/detail?cfg=wetsvoorsteldetails&qry=wetsvoorstel%3A35824>
- Kamerstukken I, 35824. (2021, April 30). [https://www.eerstekamer.nl/wetsvoorstel/35824\\_wet\\_elektronische](https://www.eerstekamer.nl/wetsvoorstel/35824_wet_elektronische)
- Karampela, M., Ouhbi, S., & Isomursu, M. (2019). Connected health user willingness to share personal health data: Questionnaire study. *Journal of Medical Internet Research*, 21(11), Article e14537. <https://doi.org/10.2196/14537>
- Karjalainen, T. (2022). All talk, no action? The effect of the GDPR accountability principle on the EU data protection paradigm. *European Data Protection Law Review*, 8(1), 19-30. <https://doi.org/10.21552/edpl/2022/1/6>
- Keuzenkamp, H. (2020, March 20). *Een programma voor regie op kwaliteitsregistraties en verbetering van data governance*. <https://open.overheid.nl/repository/ronl-bd19f42e-2b2d-4b2d-8a5a-096c2a58df72/1/pdf/een-programma-voor-regie-op-kwaliteitsregistraties-en-verbetering-van-datagovernance.pdf>
- Kindt, E. (2019). *Study on the appropriate safeguards under Article 89(1) GDPR for the processing of personal data for scientific research*. [https://edpb.europa.eu/system/files/2022-01/legalstudy\\_on\\_the\\_appropriate\\_safeguards\\_89.1.pdf](https://edpb.europa.eu/system/files/2022-01/legalstudy_on_the_appropriate_safeguards_89.1.pdf)
- KNMG-richtlijn. (2016). *Omgaan met medische gegevens*. <https://www.knmg.nl/advies-richtlijnen/knmg-publicaties/omgaan-met-medische-gegevens>
- Knoppers, B. M., Beauvais, M. J., Joly, Y., Zawati, M. N. H., Rousseau, S., Chassé, M., & Mooser, V. (2020). Modeling consent in the time of COVID-19. *Journal of Law and the Biosciences*, 7(1), Article lsa020. <https://doi.org/10.1093/jlb/lsa020>
- Knoppers, B. M., Harris, J. R., Budin-Ljøsne, I., & Dove, E. S. (2014). A human rights approach to an international code of conduct for genomic and clinical data sharing. *Human Genetics*, 133(7), 895-903. <https://doi.org/10.1007/s00439-014-1432-6>
- Kongsholm, N. C. H., & Kappel, K. (2017). Is consent based on trust morally inferior to consent based on information? *Bioethics*, 31(6), 432-442. <https://doi.org/10.1111/bioe.12342>
- Koning, M. E. (2020, September 23). *The purpose and limitations of purpose limitation* [Dissertation]. Radboud University. [https://merelkoning.nl/wp-content/uploads/2020/10/M.Koning\\_The-purpose-and-limitations-of-purpose-limitation\\_thesis.pdf](https://merelkoning.nl/wp-content/uploads/2020/10/M.Koning_The-purpose-and-limitations-of-purpose-limitation_thesis.pdf)
- Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst. (2004). *Van wet naar praktijk: Implementatie van de WGBO*. KNMG. <https://www.knmg.nl/advies-richtlijnen/knmg-publicaties/wgbo-1>
- Koops, B. J. (2011). Digitale grondrechten en de Staatscommissie: op zoek naar de kern. *Tijdschrift voor Constitutioneel Recht*, 2(2), 168-185. [https://pure.uvt.nl/ws/portalfiles/portal/1328248/Koops\\_Digitale\\_grondrechten\\_en\\_de\\_Staatscommissie\\_110509\\_postprint\\_immediately.pdf](https://pure.uvt.nl/ws/portalfiles/portal/1328248/Koops_Digitale_grondrechten_en_de_Staatscommissie_110509_postprint_immediately.pdf)

- Kop, M. (2021). *EU Artificial Intelligence Act: The European Approach to AI*. Stanford. [https://futurium.ec.europa.eu/sites/default/files/2021-10/Kop\\_EU%20Artificial%20Intelligence%20Act%20-%20The%20European%20Approach%20to%20AI\\_21092021\\_0.pdf](https://futurium.ec.europa.eu/sites/default/files/2021-10/Kop_EU%20Artificial%20Intelligence%20Act%20-%20The%20European%20Approach%20to%20AI_21092021_0.pdf)
- Kosta, E. (2013). Consent in European data protection law. In: *Consent in European Data Protection Law*. Brill Nijhoff.
- Krabben, J. A. L., (2005, March). *Onderzoek Landelijke Zorgregistraties*. College Bescherming Persoonsgegevens. [https://autoriteitpersoonsgegevens.nl/sites/default/files/downloads/rapporten/rap\\_2005\\_zorgregistraties.pdf](https://autoriteitpersoonsgegevens.nl/sites/default/files/downloads/rapporten/rap_2005_zorgregistraties.pdf)
- Kuipers, E. J. (2022a, May 9). *Herijking Grondslagen voor gegevensuitwisseling in de zorg* [Letter to Parliament]. <https://www.tweedekamer.nl/downloads/document?id=2022D17935>
- Kuipers, E. J. (2022b, May 9). *Waardevolle AI voor Gezondheid* [Letter to Parliament]. <https://open.overheid.nl/repository/ronl-ae65754d3c9e764a66bf1e843be8a6315441cad2/1/pdf/kamerbrief-over-waardevolle-ai-voor-gezondheid.pdf>
- Kuipers, E. J. (2022c, December 15). *Impactanalyses op het Commissievoorstel omtrent een European Health Data Space en beantwoording Kamervragen* [Letter to Parliament]. <https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/kamerstukken/2022/12/15/kamerbrief-over-impactanalyses-op-het-commissievoorstel-omtrent-een-european-health-data-space-en-beantwoording-kamervragen/kamerbrief-over-impactanalyses-op-het-commissievoorstel-omtrent-een-european-health-data-space-en-beantwoording-kamervragen.pdf>
- Kuipers, E.J. (2023, February 23). *Regels voor handelingen met lichaamsmateriaal, welke worden verricht voor andere doeleinden dan geneeskundige behandeling of diagnostiek van de donor (Wet zeggenschap lichaamsmateriaal)* [Letter to Parliament]. [https://www.eerstekamer.nl/behandeling/20230223/brief\\_regering\\_verzoek\\_uitstel/document3/f=/vm11ejjmm2sk.pdf](https://www.eerstekamer.nl/behandeling/20230223/brief_regering_verzoek_uitstel/document3/f=/vm11ejjmm2sk.pdf)
- Lagioia, F. (2020, June). *The impact of the General Data Protection Regulation (GDPR) on artificial intelligence*. [https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641530/EPRS\\_STU\(2020\)641530\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641530/EPRS_STU(2020)641530_EN.pdf)
- Langbroek, P. M., Van Den Bos, K., Simon Thomas, M., Milo, J. M., & van Rossum, W. M. (2017). Methodology of legal research: Challenges and opportunities. *Utrecht Law Review*, 13(3), 1-8. <https://doi.org/10.18352/ulr.411>
- Lanzing, M. (2019). “Strongly recommended” revisiting decisional privacy to judge hypernudging in self-tracking technologies. *Philosophy & Technology*, 32(3), 549-568. <https://doi.org/10.1007/s13347-018-0316-4>
- Laugesen, K., Ludvigsson, J. F., Schmidt, M., Gissler, M., Valdimarsdottir, U. A., Lunde, A., & Sørensen, H. T. (2021). Nordic health registry-based research: A review of health care systems and key registries. *Clinical Epidemiology*, 13, 533-554. <https://doi.org/10.2147/CLEP.S314959>
- Learning Hub. (n.d.). *Prospective vs. retrospective studies*. <https://learning.closer.ac.uk/learning-modules/introduction/types-of-longitudinal-research/prospective-vs-retrospective-studies/>
- Leenen, H. J. J., Gevers, J. K. M., Legemaate, J., Ploem, M. C., van der Mersch, M. F., Plomp, E., Dörenberg, V. E. T., & de Jong, E. J. C. (2020). *Handboek gezondheidsrecht*. Boom.
- Legemaate, J. (2006). *Patiëntenrechten in wetgeving en rechtspraak*. Inspectie voor de Gezondheidszorg.
- Lucivero, F., & Jongsma, K. R. (2018). A mobile revolution for healthcare? Setting the agenda for bioethics. *Journal of Medical Ethics*, 44(10), 685-689. <https://doi.org/10.1136/medethics-2017-104741>
- Lynskey, O. (2014). Deconstructing data protection: The ‘added-value’ of a right to data protection in the EU legal order. *International & Comparative Law Quarterly*, 63(3), 569-597. <https://doi.org/10.1017/S0020589314000244>
- Maessen, J. G., Peeters, R. P., Smit, E. F., Hoyng, C. B., & Bennema, M. (2019, March). *Adviesrapport Knelpunten oplossen bij opstarten van wetenschappelijk onderzoek door medisch specialisten*. Federatie

- Medisch Specialisten. [https://demedischspecialist.nl/sites/default/files/FMS-Adviesrapport-oplossen%20knelpunten%20bij\(2019\)\\_v03.pdf](https://demedischspecialist.nl/sites/default/files/FMS-Adviesrapport-oplossen%20knelpunten%20bij(2019)_v03.pdf)
- Marcus, J. S., Martens, B., Carugati, C., Bucher, A., & Godlovitch, I. (2022). The European Health Data Space. *IPOL| Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament Policy Department studies*. [https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL\\_STU\(2022\)740054\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf)
- Mheen D. van de (2019). “De kunst van co-creëren”: Kennis die er toe doet! Inaugural lecture at Tilburg University. <https://research.tilburguniversity.edu/en/publications/de-kunst-van-co-cre%C3%ABren-kennis-die-er-toe-doet>
- Milligan, E., & Jones, J. (2016). Rethinking autonomy and consent in healthcare ethics. In P. E. Clark (Ed.), *Bioethics – medical, ethical and legal perspectives*. InTech.
- Ministerie van Volksgezondheid, Welzijn en Sport. (2020, April 14). *Interne beleidslijn inzake het verzamelen van onderzoeksdata en doorgifte buiten EU vanwege COVID-19*. <https://www.datavoorgezondheid.nl/binaries/datavoorgezondheid/documenten/publicaties/2020/04/15/beleidslijn-inzake-het-verzamelen-van-onderzoeksdata-en-doorgifte-buiten-eu-vanwege-covid-19/20200415+Beleidslijn+AVG+onderzoek+en+doorgifte+Covid19.pdf>
- Ministry of Health, Welfare and Sport. (2020, October). *National Dementia Strategy 2021 – 2030*. <https://www.government.nl/binaries/government/documenten/publicaties/2020/11/30/national-dementia-strategy-2021-2030/National+Dementia+Strategy+2021+-+2030.pdf>
- Moerel, L. (2022, September 27). *What happened to the risk-based approach to data transfers?* Privacy Forum. <https://fpf.org/blog/what-happened-to-the-risk-based-approach-to-data-transfers/>
- Moerel, L., & Prins, C. (2016a). Privacy for the homo digitalis: Proposal for a new regulatory framework for data protection in the light of Big Data and the Internet of Things. *SSRN Electronic Journal*. <https://doi.org/10.2139/ssrn.2784123>
- Moerel, L., & Prins, C. (2016b). Privacy voor de homo digitalis: Proeve van een nieuw toetsingskader voor gegevensbescherming in het licht van Big Data en Internet of Things. In *Homo Digitalis. Preadviezen 2016 Nederlandse Juristen-Vereniging 2016* (pp. 9-124). Kluwer juridisch.
- Molnár-Gábor, F., Sellner, J., Pagil, S., Slokenberga, S., Tzortzatou-Nanopoulou, O., & Nyström, K. (2022). Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden. In *Seminars in Cancer Biology*, 84, 271-283. <https://doi.org/10.1016/j.semcancer.2021.12.001>
- Mondschein, C. F., & Monda, C. (2019). The EU’s General Data Protection Regulation (GDPR) in a research context. In P. Kubben, M. Dumontier, & A. Dekker (Eds.), *Fundamentals of Clinical Data Science* (pp. 55-71). Springer.
- Mostert, M., Bredenoord, A. L., Biesart, M. C., & van Delden, J. J. (2016). Big Data in medical research and EU data protection law: Challenges to the consent or anonymise approach. *European Journal of Human Genetics*, 24(7), 956-960. <https://doi.org/10.1038/ejhg.2015.239>
- Mostert, M., Bredenoord, A. L., van Der Sloot, B., & van Delden, J. J. (2018). From privacy to data protection in the EU: Implications for big data health research. *European Journal of Health Law*, 25(1), 43-55. <https://doi.org/10.1038/ejhg.2015.239>
- Mulder, T., & Tudorica, M. (2019). Privacy policies, cross-border health data and the GDPR. *Information & Communications Technology Law*, 28(3), 261-274. <https://doi.org/10.1080/13600834.2019.1644068>
- Muller, S. H., Mostert, M., van Delden, J. J., Schillemans, T., & van Thiel, G. J. (2022). Learning accountable governance: Challenges and perspectives for data-intensive health research networks. *Big Data & Society*, 9(3), Article 36797. <https://doi.org/10.2196/36797>

- Muscat, D. M., Shepherd, H. L., Nutbeam, D., Trevena, L., & McCaffery, K. J. (2021). Health literacy and shared decision-making: Exploring the relationship to enable meaningful patient engagement in healthcare. *Journal of General Internal Medicine*, 36(2), 521-524. <https://doi.org/10.1007/s11606-020-05912-0>
- Nehmelman, R., & Woltjer, A. (2010). Annotatie bij EHRM 9 april 2010 – Staat/ Clara Wichmann c.s. *NTM/ NJCM-Bull*, 35(5), 485 – 500.
- Nishimura, A., Carey, J., Erwin, P. J., Tilburt, J. C., Murad, M. H., & McCormick, J. B. (2013). Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics*, 14, Article 28. <https://doi.org/10.1186/1472-6939-14-28>
- Nissenbaum, H. (2020). *Privacy in context: Technology, policy, and the integrity of social life*. Stanford University Press.
- Nouwt, J. (2022). De Wegiz: wettelijk verplichte elektronische gegevensuitwisseling in de zorg. *Tijdschrift voor Gezondheidsrecht*, 224-239. <https://doi.org/10.5553/TvGR/016508742022046003005>
- Nys, H., Stultiëns, L., Borry, P., Goffin, T., & Dierickx, K. (2007). Patient rights in EU member states after the ratification of the Convention on Human Rights and Biomedicine. *Health Policy*, 83(2-3), 223-235. <https://doi.org/10.1016/j.healthpol.2007.02.003>
- O'Neill, O. (2003). Some limits of informed consent. *Journal of Medical Ethics*, 29(1), 4-7. <http://dx.doi.org/10.1136/jme.29.1.4>
- Organization for Economic Co-operation and Development. (1980). *OECD guidelines on the protection of privacy and trans-border flows of personal data*. [https://www.oecd-ilibrary.org/science-and-technology/oecd-guidelines-on-the-protection-of-privacy-and-transborder-flows-of-personal-data\\_9789264196391-en](https://www.oecd-ilibrary.org/science-and-technology/oecd-guidelines-on-the-protection-of-privacy-and-transborder-flows-of-personal-data_9789264196391-en)
- Organization for Economic Co-operation and Development. (2009). *OECD guidelines on human biobanks and genetic research databases*. <https://www.oecd.org/sti/emerging-tech/44054609.pdf>
- Organization for Economic Co-operation and Development. (2021). *Toward an integrated health information system in the Netherlands. Draft interim brief and recommendations*. <https://www.oecd.org/health/Integrated-health-information-system-NLD-Brief-Recommendations.pdf>
- Overkleeft, G. (1995, September 8). *De Wet persoonsregistraties: Norm, toepassing en evaluatie* [Doctoral Thesis]. Tilburg University. <https://pure.uvt.nl/ws/portalfiles/portal/810997/198256.pdf>
- Overkleeft-Verburg, G. (2000). Artikel 10. In A. Koekkoek (Ed.), *De Grondwet: Een systematisch en artikelsgewijs commentaar* (pp. 155 – 178). WEJ Tjeenk Willink.
- Patiëntenfederatie Nederland. (2021, February). *Rapport Delen van data in de gezondheidszorg*. <https://www.datavoorgezondheid.nl/binaries/datavoorgezondheid/documenten/publicaties/2021/03/31/rapport-delen-van-data-voor-de-gezondheidszorg---onderzoek-patientenfederatie-nederland/210325+Definitieve+rapportage+Delen+van+Data.pdf>
- Patiëntenfederatie Nederland (2023, July). *Rapport Zeggenschap over gezondheidsgegevens bij secundair gebruik van data*. <https://www.patiëntenfederatie.nl/downloads/rapporten/1453-definieer-rapportage-zeggenschap-gezondheidsgegevens-secundair-gebruik/file>
- Pavlakos, G. (2014). Between reason and strategy: Some reflections on the normativity of proportionality. In G. Huscroft, B. W. Miller, & G. Webber (Eds.), *Proportionality and the rule of law: Rights, justification, reasoning* (p. 90). Cambridge University Press.
- Peloquin, D., DiMaio, M., Bierer, B., & Barnes, M. (2020). Disruptive and avoidable: GDPR challenges to secondary research uses of data. *European Journal of Human Genetics*, 28(6), 697-705. <https://doi.org/10.1038/s41431-020-0596-x>
- Peolsson, M. et. al. (2023, March). *Deliverable 5.2. Recommendations for European Countries when planning national legislation on secondary use of health data*. Towards European Health Data Space

- Consortium Partners. <https://tehdas.eu/app/uploads/2023/03/tehdas-recommendations-for-european-countries-when-planning-national-legislation.pdf>
- Ploem, M. C. (2005). Freedom of research and its relation to the right to privacy. In E. H. Gevers & J. Hubben (Eds.), *Health Law, Human Rights and the Biomedicine Convention* (pp. 161-173). Brill Nijhoff.
- Ploem, M. C. (2006). Towards an appropriate privacy regime for medical data research. *European Journal of Health Law*, 13(1), 41-63. <https://doi.org/10.1163/157180906777036319>
- Ploem, M. C. (2017). Wetsvoorstel 'zeggenschap lichaamsmateriaal': Nog veel om over na te denken... *Tijdschrift Zorg & Recht in Praktijk*, 2, 21-26. <https://doi.org/10.5553/TvGR/016508742017041405002>
- Ploem, M. C., & Dute, J. C. J. (2016). Wetenschappelijk onderzoek na overlijden. Goed geregeld? *Tijdschrift voor Gezondheidsrecht*, 40(8), 498-512. <https://doi.org/10.5553/TvGR/016508742016040008002>
- Ploem, M. C. (2022). Laat de huidige wetgeving voldoende ruimte voor gegevensuitwisseling in de zorg? *Tijdschrift voor Gezondheidsrecht*, 46(3), 185-188. <https://doi.org/10.5553/TvGR/016508742022046003001>
- Ploem, M. C., Harskamp, R., van Dijk, N., Scholte, R., Hooghiemstra, T., Willems, D., & van Weert, H. C. P. M. (2020). Privacywetgeving en wetenschappelijk onderzoek. *Huisarts en wetenschap*, 63(2), 30-32. <https://doi.org/10.1007/s12445-019-0409-z>
- Ploem, M. C., Rigte, T., & Gevers, J. K. M. (2020). Medisch data-onderzoek in het AVG-tijdperk: Een zoektocht naar de juiste regels. *Tijdschrift voor Gezondheidsrecht*, 44(2), 162-181. <https://doi.org/10.5553/TvGR/016508742020044002004>
- Ploug, T., & Holm, S. (2016). Meta consent: A flexible solution to the problem of secondary use of health data. *Bioethics*, 30(9), 721-732. <https://doi.org/10.1111/bioe.12286>
- Prainsack, B., & Buyx, A. (2012). Solidarity in contemporary bioethics: Towards a new approach. *Bioethics*, 26(7), 343-350. <https://doi.org/10.1111/j.1467-8519.2012.01987.x>
- Prainsack, B. (2018). The “we” in the “me” solidarity and health care in the era of personalized medicine. *Science, Technology, & Human Values*, 43(1), 21-44. <https://journals.sagepub.com/doi/10.1177/0162243917736139>
- Quinn, P. (2017). The EU commission's risky choice for a non-risk based strategy on assessment of medical devices. *Computer Law & Security Review*, 33(3), 361-370. <https://doi.org/10.1016/j.clsr.2017.03.019>
- Quinn, P. (2021). Research under the GDPR: A level playing field for public and private sector research? *Life Sciences, Society and Policy*, 17(1), 1-33. <https://doi.org/10.1186/s40504-021-00111-z>
- Ramerman, L., van Veen, E. B., & Schermer, T. (2019). *Inventarisatie herziening gedragscode gezondheidsonderzoek: Federa-COREON & Nivel*. [https://www.nivel.nl/sites/default/files/bestanden/Eindrapportage\\_Herziening\\_Gedragscode\\_gezondheidsonderzoek.pdf](https://www.nivel.nl/sites/default/files/bestanden/Eindrapportage_Herziening_Gedragscode_gezondheidsonderzoek.pdf)
- Rebers, S., Aaronson, N. K., van Leeuwen, F. E., & Schmidt, M. K. (2016). Exceptions to the rule of informed consent for research with an intervention. *BMC Med Ethics*, 17, Article 9. <https://doi.org/10.1186/s12910-016-0092-6>
- Rebers, S., van der Valk, T., Meijer, G. A., van Leeuwen, F. E., & Schmidt, M. K. (2012). Zeggenschap over nader gebruik van lichaamsmateriaal. Patiënt is het best gediend met 'geen bezwaar'-procedure. *Nederlands Tijdschrift voor Geneeskunde*, 156, Article A4485.
- Rebers, S., Vermeulen, E., Brandenburg, A. P., Stoof, T. J., Zupan-Kajcovski, B., Bos, W. J. W., Jonker, M. J., Bax, C. J., van Driel, W. J., Verwaal, V. J., van den Brekel, M. W., Grutters, J. C., Tupker, R. A., Plusjé, L., de Bree, R., Schagen van Leeuwen, J. H., Vermeulen, E. G. J., de Leeuw, R. A., Brohet, R. M., Aaronson, N. K., van Leeuwen, F. E., & Schmidt, M. K. (2016). A randomised controlled trial of consent procedures for the use of residual tissues for medical research: Prefer-

- ences of and implications for patients, research and clinical practice. *PLoS one*, 11(3), Article e0152509. <https://doi.org/10.1371/journal.pone.0152509>
- Regulation (EU) 2014/536 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. (2014, April 16). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0536>
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). (2016, April 27). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679>
- Richter, G., Borzikowsky, C., Hoyer, B. F., Laudes, M., & Krawczak, M. (2021). Secondary research use of personal medical data: Patient attitudes towards data donation. *BMC Medical Ethics*, 22(1), Article 164. <https://doi.org/10.1186/s12910-021-0078-x>
- Richter, G., Borzikowsky, C., Lesch, W., Semler, S. C., Bunnik, E. M., Buyx, A., & Krawczak, M. (2021). Secondary research use of personal medical data: Attitudes from patient and population surveys in The Netherlands and Germany. *European Journal of Human Genetics*, 29(3), 495-502. <https://doi.org/10.1038/s41431-020-00735-3>
- Rigter, T., Jansen, M. E., van Klink-de Kruijff, I. E., & Onstwedder, S. M. (2021). *Kansen en risico's van DNA-zelftesten*. Rijksinstituut voor Volksgezondheid en Milieu RIVM. <https://www.rivm.nl/bibliotheek/rapporten/2020-0196.pdf>
- Roberts, J. S., Gornick, M. C., Carere, D. A., Uhlmann, W. R., Ruffin, M. T., & Green, R. C. (2017). Direct-to-consumer genetic testing: User motivations, decision making, and perceived utility of results. *Public Health Genomics*, 20(1), 36-45. <https://doi.org/10.1159/000455006>
- Ross, D. A., Smith, P. G., & Morrow, R. H. (2015). Types of intervention and their development. In P. G. Smith, R. H. Morrow, & D. A. Ross (Eds.), *Field trials of health interventions: A toolbox* (3<sup>rd</sup> edition, pp. 100–105). Oxford University Press.
- Rouvroy, A., & Pouillet, Y. (2009). The right to informational self-determination and the value of self-development: Reassessing the importance of privacy for democracy. In S. Gutwirth, Y. Pouillet, P. de Hert, C. de Terwangne, & S. Nouwt (Eds.), *Reinventing data protection?* (pp. 45-76). Springer.
- Sariyar, M., & Schlünder, I. (2019). Challenges and legal gaps of genetic profiling in the era of big data. *Frontiers in Big Data*, 2, Article 40. <https://doi.org/10.3389/fdata.2019.00040>
- Schäfer-Zell, W. (2022). Revisiting the definition of health data in the age of digitalized health care. *International Data Privacy Law*, 12(1), 33-43. <https://doi.org/10.1093/idpl/ipab025>
- Schermer, B. W., Custers, B., & van der Hof, S. (2014). The crisis of consent: How stronger legal protection may lead to weaker consent in data protection. *Ethics and Information Technology*, 16(2), 171-182. <https://doi.org/10.1007/s10676-014-9343-8>
- Schermer, B. W., Hagenauw, D., & Falot, N. (2018, May 25). *Handleiding Algemene verordening gegevensbescherming en Uitvoeringswet Algemene verordening gegevensbescherming*. Ministerie van Justitie en Veiligheid. [https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/handleiding\\_avg.pdf](https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/handleiding_avg.pdf)
- Schneble, C. O., Elger, B. S., & Shaw, D. M. (2020). All our data will be health data one day: The need for universal data protection and comprehensive consent. *Journal of Medical Internet Research*, 22(5), Article e16879. <https://doi.org/10.2196/16879>
- Schneider, G. (2019). Disentangling health data networks: A critical analysis of Articles 9.2 and 89 GDPR. *International Data Privacy Law*, 9(4), 253–271. <https://doi.org/10.1093/idpl/ipz015>
- Scholte, R., Kranendonk, E., Paardekooper, M., & Ploem, C. (2019). Hergebruik van patiëntgegevens voor wetenschappelijk onderzoek: Op weg naar eenduidige spelregels. *Tijdschrift voor Gezondheidswetenschappen*, 97(3), 55-58. <https://doi.org/10.1007/s12508-019-0213-y>

- Segen, J. C. (2002). *McGraw-Hill concise dictionary of modern medicine*. McGraw-Hill.
- Shevell M. D (2009). What do we call 'them'? The 'patient' versus 'client' dichotomy. *Developmental Medicine and Child Neurology*, 51(10), 770-772. <https://doi.org/10.1111/j.1469-8749.2009.03304.x>
- Smorenburg, T., Beurden, M. van, Smorenburg, C., Bol, M. & Kist, I.R., 'Casus: altijd transparant over medische informatie?' *Tijdschrift voor Gezondheidszorg en Ethiek*, 3(2021)31. [https://www.tijdschriftge.nl/art/50-6663\\_Casus-Altijd-transparant-over-medische-informatie](https://www.tijdschriftge.nl/art/50-6663_Casus-Altijd-transparant-over-medische-informatie)
- Snell, K., Tarkkala, H., & Tupasela, A. (2021). A solidarity paradox—welfare state data in global health data economy. *Health*. <https://doi.org/10.1177/1363459321106932>
- Solove, D. J., Data Is What Data Does: Regulating Based on Harm and Risk Instead of Sensitive Data (January 21, 2024). 118 *Northwestern University Law Review* 1081 (2024), GWU Legal Studies Research Paper No. 2023-22, GWU Law School Public Law Research Paper No. 2023-22. <https://ssrn.com/abstract=4322198> or <http://dx.doi.org/10.2139/ssrn.4322198>
- Solove, D. J. (2022). The Limitations of Privacy Rights. *Notre Dame L. Rev.*, 98, 975. <https://scholarship.law.nd.edu/ndlr/vol98/iss3/1>
- Solove, D. J., & Hartzog, W. (2024, forthcoming). Kafka in the Age of AI and the Futility of Privacy as Control. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4685553](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4685553)
- Stüssgen, R., Coppens, R., van Veen, E. B., Urbanus, T., & Verheij, R. (2019). Zorggegevens voor onderzoek: bezwaar of toestemming? De wet en de praktijk. Utrecht, Nivel. <https://www.nivel.nl/nl/publicatie/zorggegevens-voor-onderzoek-bezwaar-toestemming-de-wet-en-de-praktijk>
- Sugano, S. (2014). International code of conduct for genomic and health-related data sharing. *The Hugo Journal*, 8(1), 1. <https://doi.org/10.1186/1877-6566-8-1>
- Swedish act on health data registries (1998). *Lag om hälsodataregister*.
- Taylor, M. J., & Whitton, T. (2020). Public interest, health research and data protection law: Establishing a legitimate trade-off between individual control and research access to health data. *Laws*, 9(1), Article 6. <https://doi.org/10.3390/laws9010006>
- Taylor, M. J., & Wilson, J. (2019). Reasonable expectations of privacy and disclosure of health data. *Medical Law Review*, 27(3), 432-460. <https://doi.org/10.1093/medlaw/fwz009>
- The Royal Society. (2021, March 31). *Statement on data for international health emergencies: Governance, operations and skills*. <https://royalsociety.org/-/media/about-us/international/g-science-statements/G7-data-for-international-health-emergencies-31-03-2021.pdf>
- The, A.-M. (2016). *Dementie en wat er uiteindelijk echt toe doet. Naar een sociale benadering van dementie*. Dutch National Health Care Institute. <https://www.zorginstituutnederland.nl/binaries/zinl/documenten/publicatie/2016/04/06/derde-zorginstituut-nederland-lezing/Dementie+en+wat+er+uiteindelijk+echt+toe+doet.pdf>
- The Nuremberg Code (1947). (1996, December 7). *BMJ* 313(1448). <https://doi.org/10.1136/bmj.313.7070.1448>
- Thouvenin, F. (2021). Informational self-determination: A convincing rationale for data protection law? *Journal of Intellectual Property, Information, Technology and E-Commerce Law*, 12, 246 - 256. <https://ssrn.com/abstract=4521552>
- Townend, D. (2018). Conclusion: Harmonisation in genomic and health data sharing for research: An impossible dream? *Human Genetics*, 137(8), 657-664. <https://doi.org/10.1007/s00439-018-1924-x>
- Tweede Kamer der Staten-Generaal. (1998, februari 3). *Wet bescherming persoonsgegevens; Memorie van toelichting*. <https://zoek.officielebekendmakingen.nl/kst-25892-3.pdf>
- Tzortzatou, O., Slokenberga, S., Reichel, J., da Costa Andrade, A., Barbosa, C., Bekaert, S., van Veen, E.-B., Romeo-Casabona, C. M., Cathaoir, K. O., Chassang, G., Debucquoy, A., Derèze, J.-J., Dollé, L., Fält, S. E., Halouzka, R., Hartlev, M., Hisbergues, M., Hoppe, N., Huys, I., Vella Falzon,

- R. (2021). Biobanking across Europe post-GDPR: A deliberately fragmented landscape. In S. Slokenberga, O. Tzortzatzou, & J. Reichel (Eds.), *GDPR and Biobanking* (pp. 397-419). Springer.
- Uitvoeringswet Algemene Verordening Gegevensbescherming. (2018, May 16). <https://wetten.overheid.nl/BWBR0040940/2018-05-25>
- UK Data Protection Act. (2018). <https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>
- UK GDPR. (2019). Retained EU law version of the General Data Protection Regulation ((EU) 2016/679) (EU GDPR) as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by Schedule 1 to the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (SI 2019/419). <https://www.legislation.gov.uk/ukdsi/2019/9780111178300/body>
- UK Government. (2020, December 9). *National Data Strategy*. <https://www.gov.uk/government/publications/uk-national-data-strategy/national-data-strategy>
- UK Government. (2021). *Guidance National AI Strategy*. <https://www.gov.uk/government/publications/national-ai-strategy/national-ai-strategy-html-version>
- UK Government. (2022, January). *The benefits of Brexit. How the UK is taking advantage of leaving the EU* [Policy paper]. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1054643/benefits-of-brexite.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1054643/benefits-of-brexite.pdf)
- UK Parliament. (z.d.). *Retained EU law: Where next?* <https://committees.parliament.uk/work/6492/retained-eu-law-where-next/>
- United Nations. (1966, December 16). *International Covenant on Economic, Social, and Cultural Rights*. [https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg\\_no=IV-3&chapter=4](https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4)
- United Nations. (2006, December 13). *Convention on the Rights of Persons with Disabilities*. [https://treaties.un.org/pages/ViewDetails.aspx?chapter=4&clang=\\_en&mtdsg\\_no=IV-15&src=IND](https://treaties.un.org/pages/ViewDetails.aspx?chapter=4&clang=_en&mtdsg_no=IV-15&src=IND)
- Universal declaration of human rights. (1948, December 10). [https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\\_RES\\_217\(III\).pdf](https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_217(III).pdf)
- Van Agt, A. A. M., Haars, E. A., & Wiegel, H. (1979). *Nota over de vraag of een bepaling over het recht op onaantastbaarheid van het menselijk lichaam in de Grondwet zou moeten worden opgenomen*. [https://repository.overheid.nl/frbr/sgd/19781979/0000179656/1/pdf/SGD\\_19781979\\_0005523.pdf](https://repository.overheid.nl/frbr/sgd/19781979/0000179656/1/pdf/SGD_19781979_0005523.pdf)
- Van Beers, B. C. (2021). Artikel 11 - Onaantastbaarheid van het lichaam. In E. M. H. Hirsch Ballin, E. J. Janse de Jonge, & G. Leenknecht (Eds.), *Uitleg van de Grondwet* (pp. 251-278). Boom Juridisch.
- Van de Waerd, P. J. (2020). Information asymmetries: Recognizing the limits of the GDPR on the data-driven market. *Computer Law & Security Review*, 38, 105436. <https://doi.org/10.1016/j.clsr.2020.105436>
- Van Delden, J. J. M. (2010). Over de autonomie van de oudere patiënt. In J. H. Hubben, A. C. Hendriks, J. Legemaate, & B. Sluijters (Eds.), *Grondrechten in de gezondheidszorg, Liber Amicorum voor prof. mr. JKM Gevers* (pp. 103–111). Bohn Stafleu van Loghum.
- Van der Mersch, M. (2018, April 20). Nieuwe E-health toepassingen, zijn de patiëntenrechten aan innovatie toe? (Preadvisie Vereniging voor Gezondheidsrecht 2018). <https://www.vereniginggezondheidsrecht.nl/uploads/vergaderingen/2018/Jaarvergadering/9.2%20M%20vd%20Mersch.pdf>
- Van der Sloot, B. (2014). Do data protection rules protect the individual and should they? An assessment of the proposed General Data Protection Regulation. *International Data Privacy Law*, 4(4), 307-325. <https://doi.org/10.1093/idpl/ipu014>
- Van der Sloot, B. (2014). Privacy as human flourishing: Could a shift towards virtue ethics strengthen privacy protection in the age of Big Data. *Journal of Intellectual Property, Information Technology & E-Commerce Law*, 5, 230-244. <https://www.jipitec.eu/issues/jipitec-5-3-2014/4097/sloot.pdf>

- Van der Sloot, B., Van Schendel, S., & Fontanillo López, C. A. (2022). *The influence of (technical) developments on the concept of personal data in relation to the GDPR*. Tilburg University. <https://repository.wodc.nl/bitstream/handle/20.500.12832/3229/3224-influence-of-technical-developments-on-concept-personal-data-full-text.pdf?sequence=1&isAllowed=y>
- Van der Weele, S., Bredewold, F., Leget, C., & Tonkens, E. (2021). What is the problem of dependency? Dependency work reconsidered. *Nursing Philosophy*, 22(2), e12327. <https://doi.org/10.1111/nup.12327>
- Van Kolfschooten, H. (2022). The mHealth power paradox: Improving data protection in health apps through self-regulation in the European Union. In I. Cohen, T. Minssen, W. Price II, C. Robertson, & C. Shachar (Eds.), *The future of medical device regulation: Innovation and protection* (pp. 63-76). Cambridge University Press.
- Van Norman, G. A., Jackson, S., Rosenbaum, S. H., & Palmer, S. K. (Eds.). (2010). *Clinical ethics in anesthesiology: A case-based textbook*. Cambridge University Press.
- Van Rijn, M. J., & Plasterk, R. H. A. (2014, July 18). *Uitvoering van het op 13 december 2006 te New York tot stand gekomen Verdrag inzake de rechten van personen met een handicap (Trb. 2007, 169)*. <https://www.tweedekamer.nl/downloads/document?id=2014D27241>
- Van Veen, E. B. (2018). Observational health research in Europe: Understanding the general data protection regulation and underlying debate. *European Journal of Cancer*, 104, 70-80. <https://doi.org/10.1016/j.ejca.2018.09.032>
- Van Veen, E. B., Boeckhout, M., Schlünder, I., Boiten, J. W., & Dias, V. (2022). Joint controllers in large research consortia: A funnel model to distinguish controllers in the sense of the GDPR from other partners in the consortium. *Open Research Europe*, 2, Article 80. <https://doi.org/10.12688/openreseurope.14825.1>
- Van Veen, E. B. & Verheij, R.A. (2022). Further use of data and tissue for a learning health system: the rules and procedures in The Netherlands, compared to Denmark, England, Finland, France and Germany. *MLCF/Nivel*, Utrecht. <https://www.health-ri.nl/sites/healthri/files/2023-08/MLCF-Nivel%20Report%20country%20comparison%20further%20use%20final.pdf>
- Veenbrink, J. M., van de Gronden, J. W., & Glas, L. R. (2022). Juridisch Advies over het voorstel voor een Verordening betreffende de Europese ruimte voor gezondheidsgegevens (European Health Data Space). [https://www.eerstekamer.nl/eu/overig/20221121/juridisch\\_advies\\_over\\_het\\_voorstel/document3/f=/vly9n92j7tyd\\_opgemaakt.pdf](https://www.eerstekamer.nl/eu/overig/20221121/juridisch_advies_over_het_voorstel/document3/f=/vly9n92j7tyd_opgemaakt.pdf)
- Vermeulen, E., Schmidt, M. K., Aaronson, N. K., Kuenen, M., Baas-Vrancken Peeters, M. J., van der Poel, H., Horenblas, S., Boot, H., Verwaal, V. J., Cats, A., & Van Leeuwen, F. E. (2009). A trial of consent procedures for future research with clinically derived biological samples. *British Journal of Cancer*, 101(9), 1505-1512. <https://doi.org/10.1038/sj.bjc.6605339>
- Vermeulen, E., Schmidt, M. K., Aaronson, N. K., Kuenen, M., Van der Valk, P., Sietses, C., van den Tol, P., & Van Leeuwen, F. E. (2009). Opt-out plus, the patients' choice: Preferences of cancer patients concerning information and consent regimen for future research with biological samples archived in the context of treatment. *Journal of Clinical Pathology*, 62(3), 275-278. <https://doi.org/10.1136/jcp.2008.061069>
- Vermeulen, E., Schmidt, M. K., Cornel, M. C., Knoppers, B. M., van Leeuwen, F. E., & Aaronson, N. K. (2011). Connective tissue: Cancer patients' attitudes towards medical research using excised (tumour) tissue. *BioSocieties*, 6(4), 466-486. <https://doi.org/10.1057/biosoc.2011.9>
- Vinkers, C. H., van De Kraats, G. B., Biesart, M. C., & Tijdink, J. K. (2014). Is mijn patiënt wilsbekwaam? Volg de leidraad. *Nederlands Tijdschrift voor Geneeskunde*, 158, Article A7229. <https://www.ntvg.nl/system/files/publications/a7229.pdf>
- Vranken, J. (2012). Exciting times for legal scholarship. *Law and Method*, 2(2), 42-62.

- Vranken, J. B. (2011). Methodology of legal doctrinal research: A comment on Westerman. In M. van Hoecke (Ed.), *Methodologies of legal research: Which kind of method for what kind of discipline?* (pp. 111-122). Hart.
- Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg, as last amended on 10 June 2020. <https://zoek.officielebekendmakingen.nl/stb-2020-178.html>
- Wet bescherming persoonsgegevens. (2012, February 9). <https://wetten.overheid.nl/BWBR0011468/2018-05-01>
- Wet geneeskundige behandelingsovereenkomst, *WGBO*, boek 7, afdeling 5 Burgerlijk wetboek (BW). (2020, January 1). <https://wetten.overheid.nl/BWBR0005290/2020-07-01/>
- Wet kwaliteit, klachten en geschillen in de zorg. (2015, October 7). <https://wetten.overheid.nl/BWBR0037173/2023-01-01>
- Wet langdurige zorg (2014, December 3). <https://wetten.overheid.nl/BWBR0035917/2022-07-01>
- Wet medisch-wetenschappelijk onderzoek met mensen. (1998, Februari 26). <https://wetten.overheid.nl/BWBR0009408/2022-07-01>
- Wet op de beroepen in de individuele gezondheidszorg (1993, November 11). <https://wetten.overheid.nl/BWBR0006251/2022-04-01>
- Wet publieke gezondheid (2008, October 9). <https://wetten.overheid.nl/BWBR0024705/2022-10-10>
- Wet zorg en dwang psychogeriatrische en verstandelijk gehandicapte cliënten. (2018, January 24). <https://wetten.overheid.nl/BWBR0040632/2021-11-06>
- Widdershoven, G. A. (1999). Care, cure and interpersonal understanding. *Journal of Advanced Nursing*, 29(5), 1163-1169. <https://doi.org/10.1046/j.1365-2648.1999.00985.x>
- Wijne, R. P. (2020). 'De omkeringsregel in medische zaken opnieuw toegepast.' Annotation of verdict by Rechtbank Amsterdam, *patiënt X/tandarts Y*. ECLI:NL:RBAMS:2013:7837.
- Wohlin, C. (2014, May). Guidelines for snowballing in systematic literature studies and a replication in software engineering. In Proceedings of the 18th international conference on evaluation and assessment in software engineering, 1-10. <https://dl.acm.org/doi/10.1145/2601248.2601268>
- World Health Organization. (2021). *The protection of personal data in health information systems: Principles and processes for public health*. <https://apps.who.int/iris/bitstream/handle/10665/341374/WHO-EURO-2021-1994-41749-57154-eng.pdf?sequence=1&isAllowed=y>
- World Medical Association. (2013). World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. *Jama*, 310(20), 2191-2194. <https://doi.org/10.1001/jama.2013.281053>
- World Medical Association. (2017). *WMA Declaration of Taipei on ethical considerations regarding health databases and biobanks*. <https://pdf-it.dev.acw.website/please-and-thank-you?url=https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/&pdfName=wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks>
- Yeung, K., & Bygrave, L. A. (2022). Demystifying the modernized European data protection regime: Cross-disciplinary insights from legal and regulatory governance scholarship. *Regulation & Governance*, 16(1), 137-155. <https://doi.org/10.1111/rego.12401>
- Yotova, R., & Knoppers, B. M. (2020). The right to benefit from science and its implications for genomic data sharing. *European Journal of International Law*, 31(2), 665-691. <https://doi.org/10.1093/ejil/cha028>
- Zanfir-Fortuna, G., & Troester-Falk, T. (2018). *Processing personal data on the basis of legitimate interests under the GDPR: Practical cases*. Future of Privacy Forum/ Nymity. [https://fpf.org/wp-content/uploads/2018/04/20180413-Legitimate-Interest\\_FPF\\_Nymity-2018.pdf](https://fpf.org/wp-content/uploads/2018/04/20180413-Legitimate-Interest_FPF_Nymity-2018.pdf)

- Zegers, C. M., Witteveen, A., Schulte, M. H., Henrich, J. F., Vermeij, A., Klever, B., & Dekker, A. (2021). Mind your data: Privacy and legal matters in eHealth. *JMIR Formative Research*, 5(3), Article e17456. <https://doi.org/10.2196/17456>
- Zuiderveen Borgesius, F. J. (2016). Mensen aanwijzen maar niet bij naam noemen: Behavioural targeting, persoonsgegevens en de nieuwe Privacyverordening. *Tijdschrift voor Consumentenrecht en Handelspraktijken*, 2, 54-66. <https://recht.nl/proxycache.html?cid=22142>
- Zürcher, T., Elger, B., & Trachsel, M. (2019). The notion of free will and its ethical relevance for decision-making capacity. *BMC Medical Ethics*, 20, Article 31. <https://doi.org/10.1186/s12910-019-0371-0>
- Zwenne, G.-J., Duthler, A.-W., Groothuis, M., Kielman, H., Koelewijn, W., & Mommers, L. (2007). *Eerste fase evaluatie Wet bescherming persoonsgegevens. Literatuuronderzoek en knelpuntenanalyse*. Ministerie van Justitie. [https://repository.wodc.nl/bitstream/handle/20.500.12832/1589/1382a-volledige-tekst\\_tcm28-69030.pdf?sequence=2&isAllowed=y](https://repository.wodc.nl/bitstream/handle/20.500.12832/1589/1382a-volledige-tekst_tcm28-69030.pdf?sequence=2&isAllowed=y)